



NDA 20-579/S-007

Boehringer Ingelheim Pharmaceuticals, Inc.
Attention: Tacy Pack
Associate Director, Product Labeling
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT 06877

Dear Ms. Pack:

Please refer to your supplemental new drug application dated August 23, 1999, received August 25, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Flomax (tamsulosin hydrochloride) Capsules, 0.4 mg.

We acknowledge receipt of your submissions dated June 29, 1999, and January 14, 2000.

This "Changes Being Effected" supplemental new drug application provides for the addition of priapism to the **WARNINGS, PRECAUTIONS, ADVERSE REACTION** *Post-Marketing Experience* and **PATIENT INFORMATION ABOUT FLOMAX CAPSULES**; the addition of infrequent reports of palpitations, constipation and vomiting to the *Post-Marketing Experience* section; and the replacement of the listing of ingredients for the capsule imprinting ink.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted August 23, 1999, patient package insert submitted August 23, 1999). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Evelyn R. Farinas, R.Ph., M.G.A., Regulatory Project Manager, at (301)

827-4260.

Sincerely,

{See appended electronic signature page}

Susan Allen, M.D., M.P.H.

Director

Division of Reproductive and Urologic Drug Products

Office of Drug Evaluation III

Center for Drug Evaluation and Research